



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,044	11/17/2003	Richard M. Chesbrough	71202-0048	4171
20915 7590 02/27/2007 MCGARRY BAIR PC 171 MONROE AVENUE, N.W. SUITE 600 GRAND RAPIDS, MI 49503			EXAMINER SOLANKI, PARIKHA	
			ART UNIT	PAPER NUMBER
			3737	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/707,044

Applicant(s)

CHESBROUGH ET AL.

Examiner

Parikha Solanki

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/16/04.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

1. Applicant's claim of benefit from prior-filed US Patent Application No. 60/427,048 under 35 U.S.C. 119 (e) or 35 U.S.C. 120, 121 or 365 (c) is hereby acknowledged and accepted.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 16 February 2004 was filed after the mailing date of the application for patent on 17 November 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the threaded coupling of the imaging and guide elements, recited in claims 19 and 58, must be shown or the feature(s) canceled from the claim(s). In the current drawings, element 64 of Figure 4B shows insufficient detail of this feature. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

Art Unit: 3737

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following informalities:

- Line 1 of paragraph 5: Examiner suggests that the phrase “Tissue biopsies utilizing a biopsy cannula are a well-known procedure” should be corrected to read “Tissue biopsy using a biopsy cannula is a well-known procedure,” or a similar correction thereof.
- Line 2 of paragraph 19: Examiner suggests that the word “comprises” should be replaced with “, the method comprising” or a similar correction thereof.
- Line 3 of paragraph 20: Examiner suggests that the word “comprises” should be replaced with “, the apparatus comprising” or a similar correction thereof.
- Line 2 of paragraph 36: Examiner suggests that the word “withdraw” should be replaced with “withdrawal” or a similar correction thereof.

Appropriate correction is required.

### ***Claim Objections***

5. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, claim 4 recites “a portion that is one of bioabsorbable or non-bioabsorbable”. Examiner contends that this recitation encompasses any and all materials, and therefore it fails to limit the structure or function of the imaging element portion. Appropriate correction is required.

6. Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form. Specifically, claim 16 recites dependence from claim 15, which is now a non-elected claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Examiner suggests that claim 16 be amended to instead depend from claim 14, and treats the claim as if it read as such for the purposes of further examination in the remainder of this Office Action. Appropriate correction is required.

Art Unit: 3737

7. Claim 23 is objected to for reciting an element with insufficient antecedent basis. Claim 23 recites "the imaging device," an element which is not previously recited within claim 23, nor is it recited in the claim(s) from which claim 23 depends. Examiner suggests that claim 23 be amended to instead recite "the imaging element," and treats the claim as if it read as such for the purposes of further examination in the remainder of this Office Action. Appropriate correction is required.

8. Claim 27, dependent on claim 23, is objected to because it recites an element with insufficient antecedent basis. Specifically, claim 27 recites "the filament," which is not previously recited in claim 27, nor is it recited in the claim(s) from which claim 27 depends. Examiner suggests that Applicant amend claim 27 to instead depend from claim 26, and treats the claim as if it read as such for the purposes of further examination in the remainder of this Office Action. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 42 states that the lesion is located "by following the guide element". Based on the full recitation of claim 42 and the claims from which 42 depends, Examiner is unable to discern what "following the guide element" entails; likewise, the supporting written disclosure fails to provide sufficient detail to apprise one of ordinary skill in the art of how to perform this step of the invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3737

12. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "easily" and "conveniently" in claim 45 are relative terms which render the claim indefinite. The terms "easily" and "conveniently" are not sufficiently defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Foerster et al (US PG Pubs. No. 2005/0165305), hereinafter Foerster ('305).

Regarding claims 1-4, 30-33, 35-37, 40, 46, 47, Foerster ('305) discloses means and steps for localizing a tissue mass via a device comprising a marker and a connector separably connected to the marker, wherein the connector may be unthreaded from the marker by pulling the connector (Figs. 9-11). The marker and connector of Foerster ('305) constitute an imaging element and a guide element, respectively, as claimed in the instant application. Foerster ('305) shows that, when the marker is placed within the tissue mass, the connector extends exteriorly of the tissue mass, and when the connector is separated from the marker, no part of the connector extends from the tissue mass (Figs. 10 & 11). Foerster ('305) states that the marker may be visualized via any state of the art imaging system (Abstract).

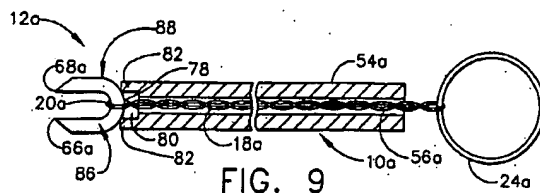


FIG. 9

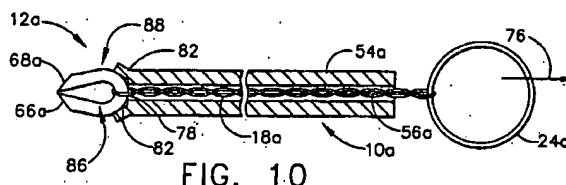


FIG. 10

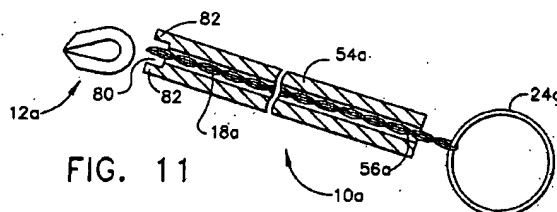


FIG. 11

Source: Foerster et al (US PG Pubs. No. 2005/0165305)

Regarding claims 5-8 and 48-50, Foerster ('305) states that the marker may be made of titanium or other biodegradable material (§ 0023, 0024, 0077).

Regarding claims 9-13 and 51-54, Foerster ('305) shows that the marker may include at least one extension, and further shows that the marker may comprise a loop through which the connector passes (Figs. 13, 14, 18).

Regarding claims 14, 26, 55 and 62, Foerster ('305) shows that the connector is a filament (Figs. 9-11).

Regarding claims 16, 27 and 63, Foerster ('305) discloses that the connector comprises a wire (§ 0020).

Regarding claims 17 and 56, Foerster ('305) states that the marker and connector are delivered to the biopsy site via a cannula, equivalent to the holder claimed in the instant application (§ 0017).

Regarding claim 18 and 57, Foerster ('305) discloses that the connector includes a failure point, at which the element may be separated from the marker after the marker has been placed in the tissue (§ 0020 & 0049, Fig. 11).

Regarding claims 19 and 58, the connector of Foerster ('305) is coupled to the marker by being threaded through the loop of the marker (Fig. 10).

Art Unit: 3737

Regarding claims 23 and 66, Foerster ('305) provides a pull ring attachable to the guide element (Figs. 9-11, element 24a). The pull ring of Foerster ('305) is equivalent to a gripping element as claimed in the instant application.

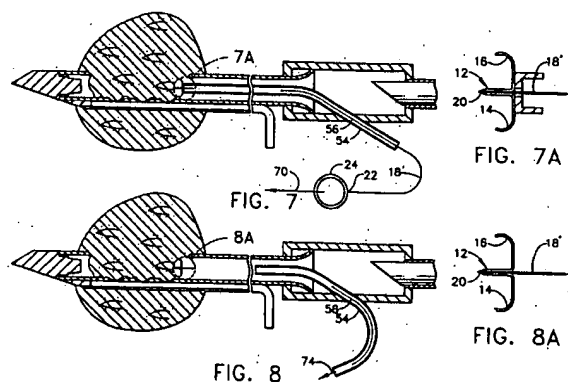
Regarding claim 24, Foerster ('305) states that the marker is releasable.

Regarding claims 3, 39 and 41, the breaking of the connector loop as shown by Foerster ('305) constitutes a cutting mechanism as claimed in the instant application (Figs. 9-11). Foerster ('305) also states that the connector is discarded after it is detached from the marker, which constitutes removing the cut portion of the guide element as claimed in the instant application (§ 0049).

Regarding claim 67, Foerster ('305) states that the delivery assembly is repositionable after release of the marker (§ 0059).

Regarding claims 69 and 70, Foerster ('305) provides cannula having a distal opening and a spring, which is slidably disposed within the lumen of the introducer, wherein the spaced is spaced inwardly from the expulsion opening prior to release of the marker into the tissue mass (§ 0057-0060). The spring of Foerster ('305) constitutes the stylet claimed in the instant application. Foerster ('305) also provides an imaging element and guide element as previously discussed for claim 1. When the spring of Foerster ('305) is advanced within the cannula, the marker is released into the tissue mass as claimed in the instant application (§ 0059).

Regarding claims 44 and 45, Foerster ('305) states that entire biopsy instrument may be mounted on a commercially available stereotactic guidance system (§ 0043). The delivery assembly components of Foerster ('305) comprise a self-contained marking apparatus as claimed in the instant application (Figs. 7-8A).



Source: Foerster et al (US PG Pubs. No. 2005/0165305)



Art Unit: 3737

**Conclusion**

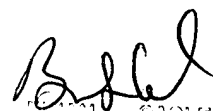
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Foerster et al (US Patent Nos. 6,228,055 & 7,044,957; US PG Pubs. Nos. 2006/0074443, 2004/0024304, 2001/0034528, 2002/0026201, 2005/0049489; EP 1304085 A2; WO 9608208 A1) disclose related devices and methods for implanting a partially bioabsorbable, imageable breast tumor marker during a biopsy procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Parikha Solanki  
Examiner - Art Unit 3737

  
Brian Casler  
Supervisor  
Art Unit 3737